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EXAMINER	
HOEKSTRA, JEFFREY GERBEN	

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/786,727	MARK, JOSEPH L.	
	Examiner	Art Unit	
	JEFFREY G. HOEKSTRA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 01/24/2008, new claim(s) 27-30 is/are acknowledged. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-8, 14-21, 27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Privatera et al. (US 6,273,862, hereinafter Privatera) in view of Moore (US 2,866,457).

4. Privatera discloses a biopsy system comprising a vacuum assisted biopsy device that communicates saline (column 18, 1st paragraph; column 21, lines 9-13) and/or an anesthetic (column 21, lines 14-16) to a piercer (70). However, Privatera does not expressly disclose a fluid connector including two check valves configured to provide the two fluids in communication with the biopsy device.

5. Moore teaches a fluid connector for the purpose of simplifying and saving time in surgical procedures (column 1, lines 34-39). The fluid connector includes a body member (9, 10, 11, 12, 13, 21, 22) having a first input port in fluid communication with a first fluid source (6), a first check valve (9) integrated within the body member and in

fluid communication with the first input port. The fluid connector further includes a second input port in fluid communication with a second fluid source (26), a second check valve (22) integrated within the body member and in fluid communication with the second input port. The fluid connector also includes an outlet port.

6. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a fluid connector as taught by Moore in the system of Privatera in order to simplify and save time in surgical procedures by avoiding the need to change fluid connections and to manually open and shut valves.

7. In regards to claim 2, Privatera and Moore do not expressly disclose a duckbill valve member. However, Moore does state that any check valve well known in the art can be used. Applicant states that a duckbill-style valve is well known (paragraph 40). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a duckbill valve member as is well known in the art in place of the valve member of Moore because it is routine in the art to substitute alternative parts.

8. In regards to claims 3 and 4, the check valves of Moore comprise resiliently compressible valve members (around and including spring 25 in figure 1) secured in a valve seat (around 25 in figure 1).

9. In regards to claims 5-7, Privatera discloses the use of an isotonic solution (saline) and an anesthetic as noted above. Moore teaches the use of a bag (6) and a needleless syringe (26) for holding fluids.

10. In regards to claim 8, the check valves taught by Moore inherently have a predetermined cracking pressure.

11. The limitations of claims 14-21 are met as noted above.

12. In regards to claims 27-30, Moore teaches the body member *further* comprising a housing comprising a unitary member (11) comprising the first input port, the second input port, the outlet port, and a fluid passageway extending through said unitary member and in fluid communication with the first input port, the second input port, the outlet port (as best seen in figure 1) (column 1 lines 63-69).

13. Claims 11, 13, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Privatera in view of Moore, as applied to claims 1-8 and 14-21 above, and further in view of Turturro et al. (US 6,331,165).

14. Privatera as modified by Moore does not expressly disclose luer fittings.

15. Turturro teaches luer fittings (column 18, lines 33-41) for the purpose of providing quick and easy connection and disconnection. Furthermore, male and female luer fittings are well known in the art and routinely used.

16. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used luer fittings as taught by Turturro and as are well known in the art to make the connections of Privatera in view of Moore in order to provide a quick and easy means to connect and disconnect the fluid sources to the check valves.

17. Claims 1-10, 12, 14-23, 25, 27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 2002/0082519, hereinafter Miller) in view of Moore.

18. Miller discloses a biopsy system comprising a vacuum assisted biopsy device, a first fluid source (400 in figure 12), and a fluid connector (around 402) configured to provide the first fluid source in communication with the biopsy device and including a check valve (402). Miller further discloses the use of a second fluid source (paragraph 90; "anesthetic"). However, Miller does not expressly disclose that the fluid connector includes a second check valve for providing the second fluid source in communication with the biopsy device.

19. Moore teaches a fluid connector for the purpose of simplifying and saving time in surgical procedures (column 1, lines 34-39). The fluid connector includes a body member (9, 10, 11, 12, 13, 21, 22) having a first input port in fluid communication with a first fluid source (6), a first check valve (9) integrated within the body member and in fluid communication with the first input port. The fluid connector further includes a second input port in fluid communication with a second fluid source (26), a second check valve (22) integrated within the body member and in fluid communication with the second input port. The fluid connector also includes an outlet port.

20. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a fluid connector as taught by Moore in the system of Miller in order to simplify and save time in surgical procedures by avoiding the need to change fluid connections and to manually open and shut valves.

21. In regards to claim 2, Miller and Moore do not expressly disclose a duckbill valve member. However, Moore does state that any check valve well known in the art can be used. Applicant states in the specification that a duckbill-style valve is well known (paragraph 40). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a duckbill valve member as is well known in the art in place of the valve member of Moore because it is routine in the art to substitute alternative parts.

22. In regards to claims 3 and 4, the check valves of Moore comprise resiliently compressible valve members (around and including spring 25 in figure 1) secured in a valve seat (around 25 in figure 1).

23. In regards to claims 5-7, Miller discloses the use of an isotonic solution (saline; paragraphs 141-144) and an anesthetic. Moore teaches the use of a bag (6) and a needleless syringe (26) for holding fluids.

24. In regards to claim 8, check valves inherently have a predetermined cracking pressure.

25. In regards to claim 9, Miller discloses that the cracking pressure is less than or equal to a vacuum created in the fluid connector by the biopsy device (paragraph 143).

26. In regards to claim 10, Moore teaches that it is desirable to keep the two fluid sources isolated and that fluid can not pass the check valves in a wrong direction (column 2, lines 15-18). Therefore, the cracking pressure is greater than a vacuum created in the fluid connector when the second check valve is open in order to prevent backflow of one fluid into the other fluid source.

27. In regards to claim 12, Miller discloses drawing a predetermined amount of fluid from a fluid source (paragraph 142).

28. The limitations of claims 14-23 and 25 are met as noted above.

29. In regards to claims 27-30, Moore teaches the body member *further* comprising a housing comprising a unitary member (11) comprising the first input port, the second input port, the outlet port, and a fluid passageway extending through said unitary member and in fluid communication with the first input port, the second input port, the outlet port (as best seen in figure 1) (column 1 lines 63-69).

Response to Arguments

30. Applicant's arguments filed 01/24/2008 have been fully considered but they are not persuasive. Applicant argues the rejections of the claims under 35 U.S.C. 103(a) as being unpatentable under Privatera in view of Moore and Miller in view of Moore. The Examiner disagrees, maintains the rejection as set forth, cited, and reiterated above, and in response notes the following:

31. For claims 1 and 14, Applicant argues Moore does not disclose, teach, and/or fairly suggest "a body member with an integral first check valve or an integral second check valve", specifically arguing the cited element of Moore are not a "body member" and the first and second check valves are not "integral" with "body member". *As broadly as structurally claimed and absent any special definition in the instant Specification*, the Examiner is treating the terms "body member" and "integral" with their

broadest reasonable interpretation within their plain meaning. The Examiner notes "body member" may be plainly defined as "any mass or portion of matter making up a structural unit" and "integral" may be plainly defined as "of, pertaining to, or belonging as a part of the whole". Using this interpretation Moore discloses and shows (as best seen in Figure 1 and cited above) a mass making up a structural unit with first and second check valves belonging as a part of the whole mass making up the structural unit.

32. Moreover, Applicant states "The elements in Moore referred to by the Examiner are not a "body member"...but a disparate collection of valve housings, fluid lines and joint housing. Furthermore, this large collection of disparate parts do not suggest a body member." The Examiner reiterates the interpretation above.

33. For claims 1 and 14, Applicant argues "Privatera nowhere teaches or suggests the desirability of a second port, let alone a second port with a valve, for use in conjunction with a biopsy device. Moore is not a biopsy device and therefore also fails to suggest nor teach the desirability of a second port, let alone a second port with a valve, for use in conjunction with a biopsy device."

34. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

35. However assuming *arguendo* Applicant argued Privatera in view of Moore "fails to suggest nor teach the desirability of a second port, let alone a second port with a valve, for use in conjunction with a biopsy device", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the fluid connect of Moore is configured to provide first and second fluid sources in communication with a medical device and is capable of providing first and second fluid sources in communication with a biopsy device.

36. For claims 1 and 14, Applicant argues Moore does not disclose, teach, and/or fairly suggest "a second fluid source is provided".

37. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "a second fluid source is provided") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

38. However, assuming *arguendo* Applicant intended to argue, Moore does not disclose, teach, and/or fairly suggest "a second fluid source in fluid communication with the second check valve and the second inlet port", the Examiner reiterates the citations above.

39. For claims 3 and 16, Applicant argues Moore does not disclose, teach, and/or fairly suggest the second check valve includes "a resiliently compressible valve member". As cited above, the check valve comprises resiliently compressible valve members (around and including spring 25 in figure 1) secured in a valve seat (around 25 in figure 1). *As broadly as structurally claimed and absent any special definition in the instant Specification*, the Examiner is treating the terms "resiliently compressible" and "valve members" with their broadest reasonable interpretation within their plain meaning. The Examiner notes "resiliently compressible" may be plainly defined as "returning to the original form or position after being in compression" and "valve members" may be plainly defined as "a structural unit for halting or controlling the flow of a liquid, a gas, or other materials through a passage, pipe, inlet, outlet, etc.". Using this interpretation Moore discloses and shows (as best seen in Figure 1 and cited above) a spring and the structure therearound for support which after being placed in compression returns to its original form that functions as a structural unit for halting or controlling the flow of a liquid, a gas, or other materials through a passage, pipe, inlet, outlet, etc.

40. For claims 8, 9, 10, 21, 22, and 23, Applicant argues Moore does not disclose, teach, fairly suggest, and/or inherently suggest a "first check valve exhibits a predetermined cracking pressure", "the cracking pressure is less than or equal to a pressure resulting from a vacuum created in the fluid connector by the vacuum assisted

biopsy device", or "the cracking pressure is greater than a pressure resulting from a vacuum created in the fluid connector by the vacuum assisted biopsy device when the second check valve is open."

41. The Examiner notes Applicant appears to heavily rely upon a product-by-process claim limitation for patentability. The product-by-process limitation a "first check valve exhibits a predetermined cracking pressure" appears to define the product by a process by which it operates. Product-by-process claim limitations are not limited to the manipulations of the recited processes, only to the structure of the product implied by the steps (MPEP 23112.01 and 2113). Attorney's argument is not the kind of factual evidence that is required to rebut a prima facie case (MPEP 2145). However, Moore discloses the implied structure comprising a check valve that functions to open and close at predetermined pressures.

42. In addition, as evidenced by Applicant in the instant Specification (see at least paragraph 40) "valve member 108 includes a flange 110 and a mouth 112 that is normally closed, but opens at a predetermined fluid pressure, commonly referred to as the "cracking pressure", to allow passage of the fluid. The cracking pressure may be tailored to a particular biopsy system application by modifying, among other features, the dimensions of mouth 112 and the flexibility of the valve member material." Moreover, Moore states (see at least column 2 lines 36-4) "Preferably, the overall length of tubing between the needle 19 and the Y-connection is made relatively short so that the flow of fluid is incapable of aspirating air into the system past the check valve 22. If it is desired to provide a more positive check, check valve 22 can be maintained in

closed position as by application of pressure from spring 25 so that it is only moved out of sealing position upon application of a positive external fluid force."

43. For claims 27-30, Applicant argues the new claimed limitations are note present. The Examiner reiterates the rejections newly set forth above.

Conclusion

44. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

45. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is

(571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

46. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

47. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey G Hoekstra/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736